BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the adoption of New)	NOTICE OF ADOPTION
Rules I and II pertaining to general)	
Medicaid services, physician)	
administered drugs)	

TO: All Interested Persons

- 1. On February 28, 2008, the Department of Public Health and Human Services published MAR Notice No. 37-432 pertaining to the public hearing on the proposed adoption of the above-stated rules, at page 376 of the 2008 Montana Administrative Register, issue number 4.
- 2. The department has adopted New Rules I (37.85.903) and II (37.85.905) as proposed.
- 3. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

<u>COMMENT #1</u>: One commentor opposed the adoption of new Rule I (ARM 37.85.903) and Rule II (ARM 37.85.905), requiring reporting of National Drug Codes (NDCs) on all physician administered drugs. The commentor complained about the high cost of implementation for its urban hospitals and clinics. In addition, the commentor stated it believes the cost to implement the billing changes, and maintain data bases and record-keeping processes outweighs any program savings to Medicaid. The commentor requests that the department suspend the proposed rule indefinitely until such time as [true] savings can be evaluated.

RESPONSE: The department does not have authority to suspend implementation of the Deficit Reduction Act of 2005 (DRA), Public Law No. 109-171 pertaining to Medicaid reimbursement for prescription drugs. Section 6002 of the DRA amends section 1903(i)(10) of the Social Security Act (the Act) by prohibiting Medicaid Federal Financial Participation (FFP) for physician administered drugs unless states submit the utilization data described in section 1927(a) of the Act. It also amends section 1927 of the Act to require the submission of utilization data for physician administered drugs. Under DRA, implementation was to have been effective January 1, 2008. The department requested additional time to implement the DRA requirements and the Centers for Medicare and Medicaid Services (CMA), the federal agency overseeing state Medicaid programs, only granted a delay until April 1, 2008.

<u>COMMENT #2</u>: Another commentor opposed adoption of new Rule I (ARM 37.85.903) and Rule II (ARM 37.85.907) due to the high cost of implementation for their rural hospitals and clinics. The commentor requested that the department

postpone implementation of the requirements for at least two years to allow the provider time for their electronic medical records system to become fully operational.

RESPONSE: The department does not have authority to postpone implementation of the Medicaid prescription drug requirements of the DRA. States are not required to participate in the Medicaid program, but if they do they must comply with the requirements of the Medicaid Act and its regulations. The department anticipates rebates of approximately \$81,396 for state fiscal year (SFY) 2008 and approximately \$325,584 for SFY 2009 with state shares of \$25,615 and \$79,777 respectively. Failure to comply would not only result in loss of the state's share of rebates but would also result in the loss of FFP for physician administered drugs. The department cannot afford the loss of FFP for failure to comply. In addition, collections of rebates will far outweigh the initial setup and maintenance costs in the long run. For a further explanation, please see the response to comment #1.

4. The department intends to apply the proposed new rules retroactively to April 1, 2008. Since the billing requirements are simply administrative, there will be no detrimental effects.

/s/ John Koch	/s/ Joan Miles
Rule Reviewer	Director, Public Health and
	Human Services

Certified to the Secretary of State April 28, 2008.